NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 23-1570

IN RE: OCUGEN, INC. SECURITIES LITIGATION

Andre Galan Bernd Benayon,
Appellant

On Appeal from the United States District Court
For the Eastern District of Pennsylvania
(District Court No. 2-21-cv-02725)
District Judge: Honorable Chad F. Kenney

Submitted Pursuant to Third Circuit L.A.R. 34.1(a)
January 29, 2024

Before: KRAUSE, PORTER, and CHUNG, Circuit Judges

(Filed: March 21, 2024)

OPINION*

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* This disposition is not an opinion of the full Court and, pursuant to I.O.P. 5.7, does not constitute binding precedent.

CHUNG, Circuit Judge.

Andre Galan Bernd Benayon, individually and on behalf of a group of similarly situated investors (collectively, "Investors"), filed an amended class action complaint against Ocugen, Inc.; its co-founder, Chief Executive Officer, and Chairman, Shankar Musunuri; and its acting Chief Medical Officer and advisor, Bruce Forrest.[1] The Investors claimed that Ocugen[2] committed securities fraud by making materially false and misleading public statements and omitting material facts regarding its ability to obtain Emergency Use Authorization ("EUA") from the United States Food and Drug Administration ("FDA") in order to quickly bring its COVID-19 vaccine, COVAXIN, to the United States market.[3] The District Court dismissed the amended complaint with prejudice for failure to state a claim. We will affirm.

I. BACKGROUND

Ocugen was a failing pharmaceutical company in dire financial straits. In late 2020, Ocugen partnered with an Indian company, Bharat Biotech, to co-develop Bharat's COVID-19 vaccine candidate, COVAXIN, for the United States market. COVAXIN is a whole-virion inactivated vaccine, meaning that the vaccine is created by chemically inactivating the live COVID-19 virus. Under Ocugen's agreement with

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[1] The initial complaint was filed on June 17, 2021. The Investors filed an amended complaint the following year, on June 13, 2022. The amended complaint is the operative complaint in this matter.

[2] The Investors brought the securities fraud claim against Ocugen, Musunuri, and Forrest. For ease of discussion, we will refer only to Ocugen.

[3] The Investors also brought a control person liability claim against Musunuri and Forrest and an insider trading claim against Musunuri. The two individual claims rely on the same allegedly false and misleading statements.

Bharat, Ocugen was to be responsible for, among other things, regulatory approval of COVAXIN, including obtaining EUA approval from the FDA.

Ocugen issued a press release informing the public about the Bharat partnership on February 2, 2021.[4] The press release stated that Ocugen had initiated discussions with the FDA "to develop a regulatory path to EUA" for COVAXIN. JA 117. Ocugen also informed securities analysts that it expected to distribute 100 million doses of COVAXIN in the U.S. in 2021. The announcements caused Ocugen's stock price to soar.

Beginning on that date and continuing until June 2021, Ocugen proceeded to issue similar statements, all essentially declaring that Ocugen was engaged in discussions with the FDA about obtaining EUA for COVAXIN, that it expected prompt EUA approval, and that it anticipated distributing mass quantities of COVAXIN in the U.S. very soon. For instance, Ocugen's SEC filings described Ocugen as engaging in "pre-EUA discussions with [the] FDA," Ocugen's plan to file for EUA in the first half of 2021, and its expectation that COVAXIN would be available in the U.S. by the second half of 2021. JA 119. Similarly, Musunuri stated in press interviews that Ocugen had initiated discussions with the FDA to pursue EUA approval and aimed to distribute 100 million doses of COVAXIN in 2021. Although the FDA revised its EUA guidance in May 2021 to provide information specific to the development of drugs for COVID-19 treatment and prevention, Ocugen reassured investors that it remained "on

[4] The class period is alleged to run from February 2, 2021, through June 9, 2021.

track" to submit an EUA application, that the new guidance did not apply to COVAXIN, and that it believed it was meeting all EUA criteria. JA 162.

Ocugen's plan to obtain EUA approval in the second half of 2021 did not come to pass. In June 2021, Ocugen issued a press release announcing that the FDA had recommended that it terminate its pursuit of the EUA path, and that Ocugen would instead pursue a Biologics License Application for COVAXIN — a change that would significantly extend its timeline for approval and distribution. The news caused Ocugen's stock price to drop dramatically. The Investors' complaint followed soon after.

II. ANALYSIS[5]

A. Securities Fraud

To state a securities fraud claim, the Investors were required to plead that: (1) Ocugen made a materially false or misleading statement or omitted a material fact needed to make a statement not misleading; (2) Ocugen acted with scienter; and (3) the Investors' reliance on Ocugen's misstatement caused them injury.[6] In re: Burlington

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[5] The District Court had jurisdiction under 28 U.S.C. § 1331 and 15 U.S.C. § 78aa. We have jurisdiction under 28 U.S.C. § 1291. We exercise plenary review of the dismissal of the amended complaint, accepting all well-pled factual allegations as true and drawing all reasonable inferences in the Investors' favor. See Nekrilov v. City of Jersey City, 45 F.4th 662, 668 (3d Cir. 2022). To survive dismissal, the amended complaint must contain sufficient factual allegations, which, taken as true, set forth a claim for relief that is plausible on its face. Id.

[6] The complaint also must satisfy the heightened fraud pleading standards of Fed. R. Civ. P. 9(b) and the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u–4(b). Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp., 394 F.3d 126, 144 (3d Cir. 2004). Rule 9(b) requires that the circumstances constituting fraud be set forth with

Coat Factory Sec. Litig., 114 F.3d 1410, 1417 (3d Cir. 1997); 15 U.S.C. § 78j(b); 17 C.F.R. § 240.10b-5. The District Court concluded that the Investors failed to plead materially false or misleading statements or omissions. We agree.

Corporate statements or failures to disclose are actionable if, when considered in light of all the information available to the market, they conveyed a false or misleading impression and the truth or disclosure was material — that is, a reasonable investor would view the information as significantly altering the total mix of available information. Fan v. StoneMor Partners LP, 927 F.3d 710, 715–16 (3d Cir. 2019). We consider whether the defendant disclosed information that would render the alleged misrepresentation or omission not misleading. Id. at 716. We also set aside subjective or vague opinions and general statements of intent or optimism as immaterial, because reasonable investors would not rely upon them in deciding how to act. In re: Aetna, Inc. Sec. Litig., 617 F.3d 272, 283 (3d Cir. 2010).

1. Alleged False and Misleading Statements

The Investors specify fifteen allegedly false and/or misleading statements, all touting that Ocugen was engaged in discussions with the FDA, that it expected speedy EUA approval, and that it anticipated distributing vast quantities of COVAXIN in 2021.

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particularity, while the PSLRA requires a securities fraud complaint to "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, [to] state with particularity all facts on which that belief is formed." In re: Rockefeller Ctr. Props., Inc. Sec. Litig., 311 F.3d 198, 217 (3d Cir. 2002) (quoting 15 U.S.C. § 78u-4(b)(1)).

The Investors claim these "profoundly optimistic statements" were false or misleading because they "communicated to investors that — at the time — there were no serious known impediments to an expeditious FDA authorization." JA 128. The Investors additionally claim that Ocugen withheld material information by "fail[ing] to disclose adverse facts about the prospects for and timing of any FDA authorization/approval of COVAXIN in the United States." JA 130. The Investors claim Ocugen withheld and/or misrepresented facts that "made a significant delay in [EUA approval] inevitable," JA 128, due to FDA guidance, including:

(1) FDA guidance for EUAs requiring "a study of a diverse cross-section of the target U.S. population," id.;

(2) FDA guidance for EUAs requiring "clear and compelling data from a well-designed Phase 3 clinical trial," id.;

(3) FDA guidance encouraging vaccine sponsors to work with the FDA at all stages of vaccine development; and

(4) FDA guidance and other government action[7] making EUA approval for an inactivated virus vaccine "extremely unlikely," id.

The Investors thus rely heavily on FDA guidance for their securities fraud claim, as they contend the guidance made it clear from the outset that Ocugen would need to undertake time-consuming U.S. clinical trials, that "an EUA pathway for COVAXIN authorization in the U.S. was extremely unlikely," id., and that authorization and distribution of COVAXIN would not be possible until at least late 2022. When the FDA

[7] The Government's Operation Warp Speed ("OWS") was a program to accelerate the development of, among other things, COVID-19 vaccines. OWS did not include inactivated virus vaccines in its development program.

guidance is considered in conjunction with Ocugen's statements, however, it is apparent that the Investors have failed to plead material falsehoods or omissions.[8]

We first consider the Investors' allegation that they were misled by Ocugen's statements indicating that it was actively engaged in discussions with the FDA to obtain EUA for COVAXIN. Although the Investors plausibly claim that the EUA path requires an applicant to work with the FDA, they fail to plead that Ocugen made any omission or misrepresentation in this regard, let alone a material one. As the District Court correctly observed, the Investors do not identify any point in the EUA process at which Ocugen did not actually engage with the FDA as it had announced.[9] The amended complaint instead relies on mere speculation and conclusory statements, which are insufficient to support a securities fraud claim. See In re: Burlington Coat Factory, 114 F.3d at 1418

We next consider the Investors' claims concerning the differences between Ocugen's approach to developing COVAXIN and the FDA's EUA guidance. We conclude that the amended complaint shows that the relevant information — namely, the

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[8] Although the Investors' claims rely on their position that the FDA's guidance was mandatory, the FDA's June 2020 guidance, November 2020 guidance, and revised May 2021 guidance all expressly stated that they were "not binding on FDA or the public" and that use of "an alternative approach [is permitted] if it satisfies the requirements of the applicable statutes and regulations." JA 321, 346, 435. Indeed, every page of each FDA guidance contains an italicized, boldface heading announcing that the document "***Contains Nonbinding Recommendations***." JA 318–41, JA 346–63, JA 432–56 (bold in original).

[9] The amended complaint acknowledges, for instance, that Ocugen submitted a Master File to the FDA in March 2021, early in the class period. If the Investors' claim is that the submission of paperwork is not sufficient to demonstrate that Ocugen was "working" or "in discussions" with the FDA, see, e.g., JA 128, they have not set forth allegations to plausibly support this view and absent such allegations, we fail to see that the distinction is material to their claim.

FDA's guidance and Ocugen's efforts — was readily available to any reasonable investor, so Ocugen's statements and/or omissions concerning the likelihood of EUA approval, even in light of these differences, would not have significantly altered the mix of information available to a reasonable investor. See Fan, 927 F.3d at 715–16.

For instance, the Investors claim that the FDA guidance can be interpreted to make EUA of an inactivated virus vaccine extremely unlikely.[10] Yet both that guidance and Ocugen's plan to market an inactivated virus vaccine were well known to investors.[11] To the extent the Investors complain that Ocugen made overly optimistic statements about its expectation of COVAXIN's EUA approval notwithstanding contrary FDA guidance, such optimism is immaterial because it is not the sort of information on which a reasonable investor would rely. See Fan, 927 F.3d at 716.

Similarly, the Investors claim Ocugen knew that the clinical trial Bharat was conducting in India would never pass muster for the EUA process and, as a result, the EUA approval timeline Ocugen had been touting would never come to be, rendering its statements anticipating EUA approval false and misleading. They contend, for instance, that Ocugen knew the FDA never would accept a study that did not include U.S. racial and ethnic minorities. They also claim the study was conducted poorly, breaching applicable protocols and guidelines. They claim Ocugen knew that these adverse facts

[10] We need not reach any conclusion on the plausibility of this proposition, although we note that we have not found any clear statement in the FDA guidance to this effect.

[11] To the extent the Investors also rely on the fact that OWS did not pursue an inactivated virus vaccine, this, too, was publicized.

would prevent EUA approval but nonetheless misled investors to expect that EUA was achievable.

Yet once again, information about the quality of the Indian COVAXIN study and the FDA's guidance concerning study protocols and diversity was readily available to any reasonable investor.[12] The amended complaint does not set forth statements or omissions by Ocugen that would have significantly altered the mix of information available to reasonable investors regarding the nature of the COVAXIN clinical study. See Fan, 927 F.3d at 715–16.

2. Falsity by Omission

The Investors also attempt to pursue a broader "overarching omission" theory, claiming that Ocugen's omissions of material information led the Investors to believe that Ocugen was adhering to the FDA's EUA guidance, when that was not the case. This theory lacks merit. As we have already discussed, Ocugen itself disclosed a great deal of information about its departures from FDA guidance, including its decision to pursue an inactivated virus vaccine and data about the clinical study of Indian participants in India. These disclosures provided information to render non-misleading

[12] As the District Court correctly observed, "even if racial diversity was a necessary requirement for EUA, reasonable shareholders were empowered with all material facts: the nature of the FDA guidance and that COVAXIN trials were taking place in India and using Indian participants." JA 23 n.14. Ocugen issued statements specifically addressing the diversity of the study participants, acknowledging that the participants all were from India but observing that they were diverse as to age, weight, body mass index, health conditions, and socioeconomic factors. Similarly, to the extent there were questions about whether the study adhered to proper protocols, the amended complaint observes that the issue was reported in the Indian media before the class period even began.

Ocugen's alleged omission of the "overarching" fact that its efforts to date did not strictly adhere to FDA guidance. See Fan, 927 F.3d at 716.

3. Omnicare Omissions

Under Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 575 U.S. 175 (2015), a reasonable investor can expect not only that a company believes its opinions, but also that the opinions are reasonably based on the information the company possesses at the time.[13] See id. at 188–89. The Investors argue that Ocugen's opinion statements were without reasonable basis because its COVAXIN strategy was not feasible in light of FDA guidance. We are not persuaded. We have already concluded that the statements of fact embedded within these opinion statements were not materially false or misleading. Additionally, we conclude that Investors have failed to sufficiently allege that Ocugen's opinions were baseless.

The Investors contend the FDA applied its guidance strictly,[14] and so Ocugen, knowing that it did not strictly adhere to the FDA's guidance, lacked a basis to announce any contrary opinion about COVAXIN's likelihood of EUA approval. To support this strict guidance theory, the Investors cite multiple statements by the FDA and other agencies indicating that rigorous scientific and ethical standards would apply to the EUA

[13] The Investors' Omnicare theory relies on the same fifteen statements anticipating EUA success and rapid COVAXIN distribution that underlie its other fraud claims. See, e.g., JA 192.

[14] As previously noted, the FDA's guidance repeated on every page that it "***Contains Nonbinding Recommendations***." JA 318–41, JA 346–63, JA 432–56 (emphasis in original).

process. But Ocugen's awareness that rigorous scientific and ethical standards would apply does not lead to the conclusion that Ocugen should also have assumed every aspect of the FDA guidelines was mandatory, despite FDA's express statements to the contrary. In addition, the amended complaint does not plausibly support a conclusion that Ocugen lacked a basis for opining that it was applying rigorous scientific and ethical principles.

One FDA statement on which the Investors rely to establish their strict compliance theory, for example, proclaimed that FDA's "goal" was to "hav[e] a diverse study population that is able to provide safety and effectiveness data across the demographic spectrum." JA 88. This statement did not define diversity, however, and clarified that the FDA "ha[s] not ever had requirements for demographic composition of data to support licensure of a vaccine and . . . it would be very difficult to outline such requirements for EUA." Id. Ocugen, meanwhile, expressed its view that its COVAXIN study in India was diverse in many ways. See JA 142 (statement by Forrest noting Indian population studied was diverse as to age, weight, body mass index, health conditions, and socioeconomic factors). Accordingly, the fact of FDA's broad goal of diversity in EUA studies does not plausibly demonstrate that Ocugen lacked a basis for opining that its COVAXIN study was diverse.

Upon review, neither this FDA statement nor any other that the Investors identify plausibly supports a conclusion that Ocugen lacked a basis for opining that COVAXIN could achieve EUA approval despite its lack of strict adherence to the FDA guidance. To the extent the Investors rely on facts that only later became known to demonstrate

that Ocugen's opinions about its expectation of EUA approval were incorrect, such as the FDA's eventual determination that Ocugen must conduct a clinical study in the U.S., hindsight does not substitute for contemporaneous knowledge in a securities fraud case. See In re: NAHC, Inc. Sec. Litig., 306 F.3d 1314, 1330 (3d Cir. 2002).

In sum, we are not persuaded by the Investors' arguments on appeal. We agree with the District Court that the amended complaint failed to set forth a plausible claim that Ocugen engaged in securities fraud by making material misrepresentations and/or omissions about its pursuit of EUA approval for COVAXIN.

B. Other Claims

The District Court properly dismissed the Investors' control person liability and insider trading claims as well. As we have already discussed, the Investors failed to plead a predicate securities fraud claim. Because a viable claim of securities fraud was necessary to support the control person liability and insider trading claims against Musunuri and Forrest, the two individual claims were properly dismissed. See City of Edinburgh Council v. Pfizer, Inc., 754 F.3d 159, 177 (3d Cir. 2014).

C. Futility of Amendment

The District Court denied the Investors' request to file a second amended complaint because they failed to suggest any factual developments that would cure the deficiencies of the complaint. We see no abuse of discretion in that determination. A District Court need not grant leave to amend when the party seeking such leave does not attach a draft amended complaint to its motion or explain how it would amend the pleading. In re: Allergan ERISA Litig., 975 F.3d 348, 358 (3d Cir. 2020).

III. CONCLUSION

For the foregoing reasons, we will affirm the judgment dismissing the amended complaint with prejudice for failure to state a claim.